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FROM : Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP

DATE : May 20, 2008

SUBJECT : U.S. Patent Appln. Serial No. 10/666,863
for *Fatigue Resistant Medical Devices*
Inventors: Walak et al.
Our Ref.: 10123/00401

NUMBER OF PAGES INCLUDING COVER : 19

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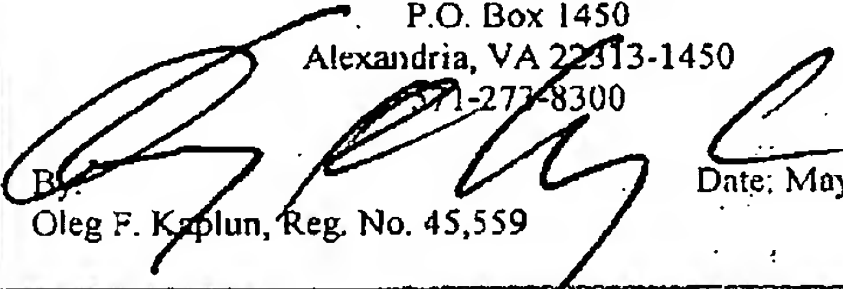
Attorney Docket No. 10123/00401 (03-079US)

MAY 20 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Walak et al.
Serial No. : 10/666,863
Filing Date : September 17, 2003
For : Fatigue Resistant Medical Devices
Group Art Unit : 1793
Confirmation No. : 8458
Examiner : George P. Wyszomierski

Mail Stop: Appeal Brief - Patent
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By:  Oleg F. Kaplun, Reg. No. 45,559	Date: May 20, 2008

TRANSMITTAL

Transmitted herewith please find a Reply Brief in response to the Examiner's Answer mailed on March 20, 2008 for filing in the above-identified application. No fees are believed to be required. The Commissioner is hereby authorized to charge any additional required fees to the **Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492**. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: May 20, 2008

By: 

Oleg F. Kaplun, Reg. 45,559

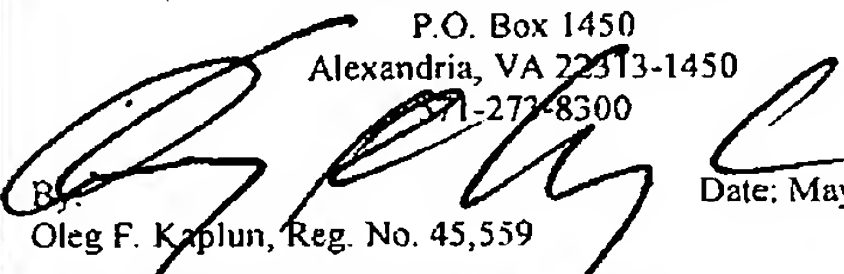
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Attorney Docket No. 10123/00401 (03-079US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Walak et al.
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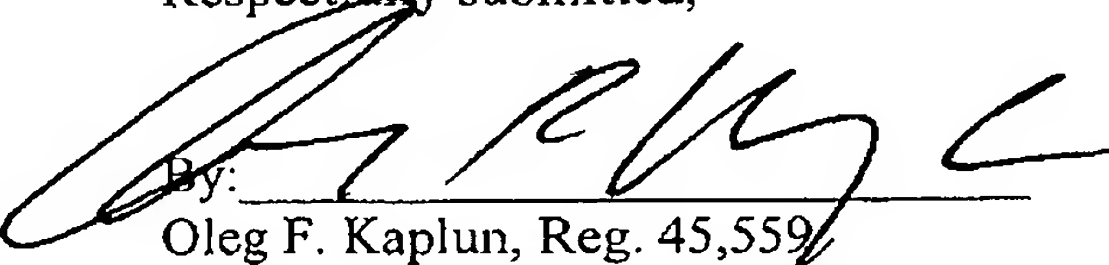
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MAY 20 2008 PATENT

Attorney Docket No.: 10123 - 00401

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:

Walak et al.

Serial No.: 10/666,863

Filed: September 17, 2003

For: FATIGUE RESISTANT MEDICAL
DEVICES

Group Art Unit: 1742

Examiner: George P. Wyszomierski

**Board of Patent Appeals and
Interferences**

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Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed on March 20, 2008 to the Appeal Brief filed on February 26, 2008 and pursuant to 37 C.F.R. § 41.41, Appellants present this Reply Brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 23 in the Final Office Action dated August 27, 2007. The appealed claims are set forth in the attached Claims Appendix.

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Group Art Unit: 1742

Attorney Docket No.: 10123 - 00401

1. Status of the Claims

Claims 1 - 23 stand rejected in the Final Office Action. Claims 24 and 25 have been withdrawn from consideration. The final rejection of claims 1 - 23 is being appealed.

2. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1 - 8, 15 - 19 and 22 are unpatentable under 35 U.S.C. § 103(a) as obvious over Frantzen (U.S. Patent No. 5,514,115) or over the '045 application (International Published Application No. WO 02/36045).
- II. Whether claims 2, 9 - 13, 20 and 21 are unpatentable under 35 U.S.C. § 103(a) as obvious over Frantzen or the '045 application in view of Flomenblit (U.S. Patent No. 5,964,770).
- III. Whether claims 1, 3 - 8, 14 - 19, 22 and 23 are unpatentable under 35 U.S.C. § 103(a) as obvious over Boyle (U.S. Patent No. 6,923,829).
- IV. Whether claims 2, 9 - 13, 20 and 21 are unpatentable under 35 U.S.C. § 103(a) as obvious over Boyle in view of Flomenblit.

3. Argument

- I. The Rejection of Claims 1 - 8, 15 - 19 and 22 Under 35 U.S.C. § 103(a) as Obvious Over Either Frantzen or the '045 application
Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1 - 8, 15 - 19 and 22 were rejected under 35 U.S.C. 103(a) as obvious over either Frantzen or the '045 application. (See 8/27/07 Office Action, p. 2). The Examiner stated that both Frantzen and the '045 disclose a medical device including Nitinol alloys portions of which are in a martensitic state while other portions are an austenitic state.

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(*Id.*) The Examiner further indicated that portions of the prior art device can be subjected to different levels of strain. (See 3/20/08 Examiner's Answer, pp. 7 - 8).

- B. Neither Frantzen nor the '045 application Shows or Suggests High Strain Portions and Lesser Strain Portions as Recited in Claim 1 or a Super-elastic Core Portion and a Fatigue-Resistant Portion as Recited in Claim 16
-

Claim 1 recites a flexible device comprising "a metallic element including high strain portions and lesser strain portions, wherein the high strain portions are to be *subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions*, the high strain portions comprising a material which is *stabilized in a martensite phase when deployed in the body* and the lesser strain portions comprise a material which, under the predetermined operating conditions, is in an austenite phase." (Emphasis added).

It is submitted that Frantzen fails to teach or suggest the placement of a martensite stabilized material in "high strain portions" and a material which, under the predetermined operating conditions, is *in an austenite phase* in lesser strain portions, wherein the martensite portions are subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions. Rather, Frantzen describes evenly distributing martensite and austenite portions along the housing, irrespective of the levels of strain to which these portions of the device will be subjected. (See Frantzen, col. 7, ll. 33 - 38; Fig. 4, 7). Specifically, the Frantzen device is provided with one of a plurality of heat treated cylindrically shaped tubular sections 40 and an elongated strip 50 to provide improved housing flexibility." (See Frantzen, col. 7, ll. 3 - 6, ll. 33 - 38; Fig. 7). It is noted that, in both of these embodiments, Frantzen discloses the placement of martensite portions of Nitinol evenly distributed along the length of the housing irrespective of a level of strain to which these portions will be subjected. (*Id.* at Figs. 4, 7)

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In regard to the recitation of high strain and lesser strain portions, the Examiner stated that claim 1 does not recite that the device has undergone any strain and that one skilled in the art could subject specific portions thereof to differing levels of strain. (*Id.*). However, it is submitted that the Examiner's argument seems to contemplate a device designed only to be purposely subjected to random strain. (See 3/20/08 Examiner's Answer, pp. 7 - 8). In fact, the recited device includes portions which *during use* (i.e., when serving a purpose for which the device is designed) are subjected to increased or lesser levels of strain. As is understood by those skilled in the art, the designers of products commonly identify portions of a device which will be subjected during use to increased or reduced levels of strain in order to adapt the design to these conditions. It is respectfully submitted that claim 1 explicitly recites a "flexible device comprising a metallic element including *high strain portions* and lesser strain portions, wherein the high strain portions are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions" wherein it is evident that such placement is made on the basis of where a strain will be exerted when the device is deployed in the body. Specifically, the recitation of the term "high strain portions" clearly indicates that the martensite material is positioned in portions of a device previously identified as areas which will be subjected during use to higher levels of strain than the lesser strain portions.

It is respectfully submitted that Frantzen fails to teach or suggest any different treatment for areas of its device which, during use, will be subjected to higher or lesser levels of strain, much less including in these high strain portions "a material which is stabilized in a martensite phase when deployed in the body" while including in the lesser strain portions "a material which, under the predetermined operating conditions, is in an austenite phase," as recited in claim 1 and that claim 1 is allowable over Frantzen. Because claims 2 - 8 and 15 depend from and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

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Claim 16 recites a medical implant comprising “a *super-elastic core portion* of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a *fatigue resistant surface portion* primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized.” (Emphasis added).

The Examiner stated that Frantzen describes an embodiment including a portion in a stable martensite phase at body temperature. (See 3/20/08 Examiner’s Answer, p. 8). However, it is submitted that Frantzen has failed to point to any teaching or suggestion in Frantzen of a “super-elastic core portion” separate from a “fatigue resistant surface portion,” as recited in claim 16. Rather, Frantzen clearly mentions the employment of either an entirely martensitic housing or an entirely austenitic housing. (See Frantzen, col. 3, ll. 16 - 30; Figs. 4 - 10). It is respectfully submitted that, even if the Examiner’s assertion that Frantzen discloses the placement of martensite and austenite portions were correct, Frantzen fails to teach a super-elastic core portion separate from a fatigue resistant surface portion. Specifically, nowhere does Frantzen make a distinction between a material/phase of a core portion versus that of a surface portion. Rather, Frantzen seeks only to provide austenitic or martensitic portions along selected portions of the *surface* of each of the embodiments taught therein with no mention of a different material for a core portion thereof. (See Frantzen, col. 7, ll. 3 - 54; Figs. 4 - 10) Furthermore, it is noted that it would not be possible to modify the Frantzen device to include a “super-elastic core portion,” as recited in claim 16 as the housing 17 of Frantzen is intended to be hollow to slidably receive a cutting blade therein. (See Frantzen, col. 5, li. 63 to col. 6, li. 9; Figs. 1 - 10).

Accordingly, it is respectfully submitted that Frantzen neither shows nor suggests a “super-elastic core portion” with a “fatigue resistant surface portion,” as recited in claim 16 and that claim 16 and its dependent claims 17 - 19 and 22 are allowable.

As with Frantzen, the ‘045 application makes no mention of strain as a deciding factor in

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the placement of superelastic portions and it is submitted that any suggestion that the locations of these plastically deformable portions is based on the location of higher and lesser strain portions is unsupported by the '045 application. Specifically, the '045 application purports to describe an endoluminal device such as a stent comprising at least one superelastic section and at least one plastically deformable section. (See '045 application, p. 3, ll. 1 - 2). Various embodiments of the '045 application include superelastic portions disposed along various longitudinal lengths of the device, the placement of the superelastic portions being designed to allow the device to "be tailored to conform to the anatomy of a lumen in which it is deployed by deforming the plastically deformable section of the device without changing the characteristics of the superelastic section of the device." (See *Id.*, p. 17, ll. 4 - 14; Figs. 1, 4A - 4F, 7A - 7F). As noted above, claim 1 explicitly recites the placement of martensite and austenite materials in higher and lesser strain portions (i.e., portions of a device identified as those to be subjected during use to increased or decreased levels of strain). The '045 application, on the other hand, teaches the placement of the plastically deformable (martensite) portions based not on a level of strain to which these portions will be subjected but, based on the specific anatomy within which the device will reside to more evenly distribute flexibility along the length of the device.

Furthermore, as noted above with regard to Frantzen, the Examiner has indicated that increased strain may be selectively applied to any portion of a device comprising a martensite portion, further affirming that the '045 application itself does not teach or suggest the *placement* of martensite and austenite portions with respect to levels of strain to which these portions will be subjected when deployed in the body. (See 3/20/08 Examiner's Answer, pp. 7 - 8). For these reasons, it is respectfully submitted that claim 1 and dependent claims 2 - 8 and 15 are allowable over the '045 application.

The '045 application also fails to teach or suggest a medical device comprising a "super-elastic core portion" separate from a "fatigue resistant surface portion", as recited in claim 16.

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Rather, the '045 application is directed to providing super-elastic portions and fatigue resistant portions on a surface thereof. (See '045, p. 3, ll. 6 - 11; Figs. 1, 4A - 4C, 5A - 5C, 6). Specifically, the '045 application teaches the placement of super-elastic and plastically deformable sections in an alternating longitudinal pattern, to allow for the radial expansion of the device. (*Id.*, see also, p. 9, ll. 11 - 22). The '045 application does not teach or suggest a fatigue-resistant surface portion. Rather, employing a fatigue-resistant surface portion in the '045 application would be detrimental thereto as it would hinder the radial expansion of the device. (See '045, p. 2, li. 31 to p. 3, li. 11).

Accordingly, Appellants respectfully submit that the '045 application does not teach or suggest a medical implant comprising a super-elastic core portion "primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase" and a fatigue resistant surface portion "primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized," as recited in claim 16 and that claim 16 and its dependent claims 17 - 19 and 22 are allowable over the '045 application.

II. The Rejection of Claims 2, 9 - 13, 20 and 21 Under 35 U.S.C.
§ 103(a) as Obvious over Frantzen or the '045 application in view of
Flomenblit Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 2, 9 - 13, 20 and 21 were rejected under 35 U.S.C. 103(a) as unpatentable over the Frantzen or the '045 application in view of Flomenblit. (See 8/27/07 Office Action, p. 3).

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B. Neither Frantzen nor the '045 application, nor
Flomenblit Either Shows or Suggests High and
Lesser Strain Portions as Recited in Claim 1 or a
Super-elastic Core as Recited in Claim 16

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Frantzen or the '045 application. Claims 2 and 9 - 13 depend from and therefore include all the limitations of independent claim 1. As discussed above, neither Frantzen nor the '045 application teaches or suggests the limitations of independent claim 1 and claim 1 is allowable over Frantzen and the '045 application. Flomenblit fails to cure the deficiencies of Frantzen and the '045 application noted above. Accordingly, because claims 2 and 9 - 13 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable for the same reasons. Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claims 2 and 9 - 13.

Claim 16 has also been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Frantzen or the '045 application. Claims 20 and 21 depend from and therefore include all the limitations of independent claim 16. As discussed above, neither Frantzen nor the '045 application teach or suggest the limitations of independent claim 16 and claim 16 is allowable over Frantzen and the '045 application. Flomenblit fails to cure the deficiencies of Frantzen and the '045 application note above. Accordingly, it is respectfully submitted that claims 20 and 21 which depend from and, therefore, include all of the limitations of independent claim 16, are allowable for the same reasons stated above in regard to claim 16. Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claims 20 and 21

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III. The Rejection of Claims 1, 3 - 8, 14 - 19, 22 and 23 Under 35
U.S.C. § 103(a) as Obvious over Boyle Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 3 - 8, 14 - 19, 22 and 23 were rejected under 35 U.S.C. 103(a) as obvious over Boyle. (See 8/27/07 Office Action, pp. 3 - 4).

B. Boyle does not Disclose High Strain Portions and
Lesser Strain Portions as Recited in Claim 1

Boyle purports to describe endoluminal devices "having regions that are either plastically deformable or are sufficiently martensitic to behave pseudoplastically in vivo, and regions that are elastically deformable or sufficiently austenitic to behave pseudoelastically or superelastically in vivo." (See Boyle, col. 4, ll. 16 - 21). The only descriptions in Boyle regarding the placement of martensitic and austenitic materials pertain to the maximization of plastic deformability. (See Boyle, col. 4, ll. 30 - 45). Boyle does not disclose or suggest the placement of martensitic portions based on an amount of strain to which a particular portion of the device will be subjected during use. As noted above with regard to the 35 U.S.C. § 103(a) rejection of claim 1 over Frantzen or the '045 application, claim 1 is directed to the placement of martensite and austenite materials in high and lesser strain portions (i.e., portions of the device identified as those which will be subjected during use to higher or lower levels of strain).

In the same manner applied above in regard to Frantzen and the '045 application, the Examiner states in support of this rejection, that one may selectively apply greater or lesser strains to various portions of the device. (See 3/20/08 Examiner's Answer, pp. 7 - 8). However, it is submitted that the Examiner's interpretation still fails to overcome the limitations of claim 1, which stress the requirement that martensite stabilized and austenite materials be placed, respectively, in high and lesser strain portions of the device (i.e., portions of the device identified

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as those which will be subjected to increased or decreased levels of strain during use). Accordingly, it is noted that Boyle does not teach a metallic element in which high strain portions (i.e., those to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions) “comprising a material which is *stabilized in a martensite phase*” and lesser strain portions comprising “a material which, *under the predetermined operating conditions, is in an austenite phase*,” as recited in claim 1 and that claims 1 and its dependent claims 3 - 8 and 14 - 15 are therefore allowable.

Claim 16 recites “*a super-elastic lesser strain core portion of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a fatigue resistant high strain surface portion primarily formed of Nitinol which, at body temperature, is substantially martensite phase stabilized, wherein the high strain portion is to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portion.*” As noted above with respect to the 35 U.S.C. § 103(a) rejection of claim 16 under Frantzen and the ‘045 application, claim 16 specifically recites that a core portion of a medical device is formed of a super-elastic Nitinol material while a surface portion thereof is formed of a fatigue resistant martensitic material. It is submitted that the only disclosure Boyle makes with respect to the placement of austenitic and martensitic portions denotes that they be placed in a pattern on a surface of the endoluminal stent 10. (See Boyle, col. 7, ll. 15 - 37; Figs. 1 - 3). Boyle does not teach or suggest forming a super-elastic core portion separate from a fatigue resistant surface portion. It is therefore submitted that Boyle fails to teach or suggest the limitations of claim 16 and claim 16 is allowable over Boyle. Because claims 17 - 19, 22 and 23 depend from, and therefore include all of the limitations of claim 16, it is submitted that these claims are also allowable.

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Group Art Unit: 1742

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IV. The Rejection of Claims 2, 9 - 13, 20 and 21 Under 35 U.S.C.
§ 103(a) as Obvious over Boyle in view of Flomenblit Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 2, 9 - 13, 20 and 21 were rejected under 35 U.S.C. 103(a) as obvious over Boyle in view of Flomenblit. (See 8/27/07 Office Action, p. 4).

B. Neither Boyle nor Flomenblit Discloses or Suggests
Either Higher and Lesser Strain Portions as Recited
in Claim 1 or a Super-elastic Core Portion as
Recited in Claim 16

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Boyle. Claims 2 and 9 - 13 depend from and therefore include all the limitations of independent claim 1. As discussed above, Boyle does not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Boyle. Flomenblit does not cure the deficiencies of Boyle noted above. Accordingly, it is respectfully submitted that claims 2 and 9 - 13 are allowable for the same reasons stated in regard to claim 1.

Claim 16 has been recited above and discussed with reference to the 35 U.S.C. § 103(a) rejection under Boyle. Claims 20 and 21 depend from and therefore include all the limitations of independent claim 16. As discussed above, Boyle does not teach or suggest the limitations of independent claim 16 and claim 16 is therefore allowable over Boyle. Flomenblit does not cure the deficiencies of Boyle noted above. Accordingly, it is respectfully submitted that claims 20 and 21 are allowable for the same reasons stated in regard to claim 16.

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4. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 103(a) and indicate that claims 1 - 23 are allowable.

Respectfully submitted,

Date: May 20, 2008

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Serial No.: 10/666,863
Group Art Unit: 1742
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CLAIMS APPENDIX

1. (Previously Presented) A flexible device comprising a metallic element including high strain portions and lesser strain portions, wherein the high strain portions are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions, the high strain portions comprising a material which is stabilized in a martensite phase when deployed in the body and the lesser strain portions comprise a material which, under the predetermined operating conditions, is in an austenite phase.
2. (Original) The device according to claim 1, further comprising a transition portion disposed between and providing a transition between the high strain and lesser strain portions.
3. (Original) The device according to claim 1, wherein the element is formed substantially of Nitinol.
4. (Original) The device according to claim 1, wherein an austenite transition temperature of the high strain portion is greater than an austenite transition temperature of the lesser portion.
5. (Original) The device according to claim 1, wherein the device is a medical device to be inserted within a living body.
6. (Original) The device according to claim 5, wherein an austenite transition temperature of the high strain portion is greater than a body temperature of the living body into which the device is to be inserted.

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7. (Original) The device according to claim 6, wherein the austenite transition temperature of the high strain portion is greater than 37 C .
8. (Original) The device according to claim 1, wherein the high strain portion is a plastically deformed surface portion of the element.
9. (Original) The device according to claim 1, wherein the high strain portion is a surface portion of the element which has been treated with an ion implantation process.
10. (Original) The device according to claim 9, wherein the high strain portion is a surface portion of the element which has been treated with an ion implantation process.
11. (Original) The device according to claim 9, wherein the high strain portion includes at least a portion of a surface of the element into which ions of one of Pd, Pt, Au, Cu, Hf, Zr, Nb, Ta and Ti have been implanted.
12. (Original) The device according to claim 1, wherein the high strain portion is a doped surface portion of the element.
13. (Original) The device according to claim 12, wherein the high strain portion includes at least a portion of a surface of the element in which one of Pd, Pt, Au, Cu, Hf, Zr, Nb, Ta and Ti has been added.
14. (Original) The device according to claim 1, wherein a titanium concentration in the high strain portion is greater than a titanium concentration in the lesser strain portion.

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15. (Original) The device according to claim 8, wherein the plastically deformed portion is one of a shot peened surface and an extruded surface of the element.
16. (Previously Presented) A medical implant comprising a structural element defining a shape of at least a portion of the implant, a super-elastic core portion of the element being primarily formed of Nitinol which, at body temperature, is in a substantially austenitic phase and a fatigue resistant surface portion primarily formed of Nitinol which, at body temperature, is substantially Martensite phase stabilized.
17. (Original) The implant according to claim 16, wherein the element is one of a wire, tubing and a sheet.
18. (Original) The implant according to claim 16, wherein at least a portion of a surface of the element is plastically deformed.
19. (Original) The implant according to claim 18, wherein the plastically deformed portion of the surface is one of shot peened and low temperature extruded.
20. (Original) The implant according to claim 16, wherein the fatigue resistant surface portion is treated with an ion implantation process.
21. (Original) The implant according to claim 16, wherein the fatigue resistant surface portion is doped with one of Pd, Pt, Au, Cu, Hf, Zr, Nb, Ta and Ti.
22. (Original) The implant according to claim 16, wherein the fatigue resistant surface portion is a cladding layer formed around the super-elastic core portion.

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23. (Original) The implant according to claim 19, wherein the fatigue resistant surface portion has a ratio of nickel and titanium modified with respect to that of the super-elastic core portion.
24. (Withdrawn) A method of forming an element of a medical device comprising the steps of:
- forming an element of the device of Nitinol;
- impressing a memorized shape on the element, wherein the memorized shape is a shape the element is to assume when in an operational configuration; and
- treating a high strain portion of the element so that the high strain portion is substantially Martensite phase stabilized under expected operating conditions of the device, wherein untreated portions of the element are in a substantially austenitic phase under the expected operating conditions.
25. (Withdrawn) The method of claim 24, wherein the high strain portion is substantially Martensite phase stabilized by plastic deformation.